



CHAPTER V

PRESENTATION

EVALUATION OF PARASITE LACTATE DEHYDROGENASE (pLDH) ASSAY (OPTIMAL-IT) FOR DETECTION OF MALARIA ON THAI-BURMESE BORDER

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Background

- Malaria is one of major public health problems on the western Thailand
- Tak, Mae Hong Sorn, Kanchanaburi reported 90% of malaria cases in Thailand
- Drug resistant falciparum malaria most occurred on the Thailand border region
- Early diagnosis & prompt artemisinin based therapy are effective for malaria control

Background (cont.)

- Malaria symptoms are very non-specific
- Microscopy diagnosis is informative and considered as gold standard
- Reliable microscopy is very difficult to access in remote areas
- Rapid Diagnosis Tests (RDTs) have been introduced a new dimension to diagnosis and treatment

Rapid Diagnosis Tests(RDTs)

- New perspective in the diagnosis of malaria
- Easy and quick to perform
- Do not require extensive training
- False negative associated with low parasitaemia (< 100 parasites/microliter of blood)
- Interpretation of a result can be difficult
- Price range US\$ 0.5-3 per test

Rapid Diagnosis Tests(cont.)

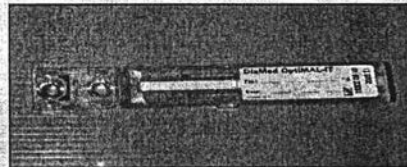
- Histidine-rich protein II e.g. ICT *Pf/Pv* (AMRAD, Australia), Paracheck Pf (Orchid Biomedical Systems, India)
- Only *P. falciparum* releases HRP- II
- The test gives negative result to *P. vivax*, *P. ovale*, *P. malariae*
- HRP- II persist in blood long after parasites clearance

Rapid Diagnosis Tests(cont.)

- Parasite Lactate Dehydrogenase (pLDH) e.g. OptiMAL (Diamed, Switzerland)
- The test can detect *P. falciparum* and *non-P. falciparum*
- More expensive than Paracheck Pf
- After treatment, give negative result more quickly than HRP II assay

Rationale

- Evaluate 2 different rapid tests against microscopy
 - Optimal-IT (pLDH detecting assay) for PF and non-PF
 - Paracheck-Pf (HRP-II detecting assay) for PF only

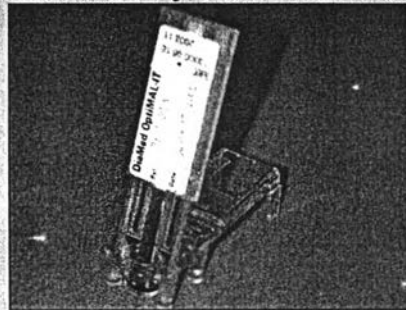


Study design and variables

- Cross-sectional descriptive study
- Specific objectives: To assess sensitivity, specificity, NPV, PPV of OptiMAL-IT
- Independent variables: Parasitaemia level
- Dependent variables: Diagnostic characteristics of OptiMAL-IT

Study Site & Duration

- Ban Mor Ker Thai
PopPhra district, Tak province, Thailand
during June 17 to July 7, 2002



Inclusion & Exclusion Criteria

- Fever & clinically suspected for malaria presenting at the OPD
- Age > 2 years old
- No pregnancy
- Consent to the study



METHOD

- 2 Set of malaria slides (Thick and Thin smear)
- OptiMAL-IT, Paracheck and Hct
- Blinded study
- 1ST M/S: on-site and rechecked blindly at SMRU
- 2nd M/S: stained in Mae Sod and kept for further investigation
- Treatment based on microscopy results

Results

- Total consented = 271
- Age 2-81 years, mean = 24 years, SD = 14.6
- Male:Female = 1.7:1
- From microscopy,
 - 53% (144/271) were positive
 - 53% (77/144) *P. vivax* only
 - 35% (50/144) *P. falciparum* only
 - 5/144 *P. malariae* only
 - 2/144 *P. ovale* only
 - 9/144 Mixed infection mainly PF+PV

OptiMAL-IT Performance to PF

Global sensitivity $52/59 = 88.1\%$
(95% CI, 77.1-95.1)

Global specificity $190/207 = 91.8\%$
(95% CI, 87.2-95.1)

PPV $52/69 = 75.4\%$ (95% CI, 63.6-84.9)

NPV $190/197 = 96.4\%$ (95% CI, 92.8-98.6)

Paracheck Performance to PF

Global sensitivity $53/59 = 89.9\%$
(95% CI, 79.2-96.2)

Global specificity $201/210 = 95.7\%$
(95%CI, 92.0-98.0)

PPV $53/62 = 85.5\%$ (95%CI, 74.2-93.1)

NPV $201/207 = 97.1\%$ (95%CI, 93.8-98.9)

Comparison of OptiMAL-IT & Paracheck to PF Detection

	OptiMAL-IT	Paracheck	p value
Sensitivity	88.1	89.9	0.76
Specificity	91.8	95.7	0.10
PPV	75.4	85.5	0.15
NPV	96.4	97.1	0.71

OptiMAL-IT Performance to non-PF

Global sensitivity $56/86 = 65.1\%$
(95% CI, 54.0-75.1)

Global specificity $178/180 = 98.9\%$
(95% CI=96.0-99.9)

PPV $56/58 = 96.6\%$ (95% CI, 88.1-99.6)

NPV $178/208 = 85.6\%$ (95% CI, 80.1-90.1)

Sensitivity & Parasitaemia

OptiMAL to PF	OptiMAL to non-PF	Parasitaemia / μ L	Paracheck to PF
100%	100%	>50,000 n=20	100%
100%	96%	5,000-50,000 n=37	100%
100%	82%	500-5,000 n=37	100%
70%*	64%	100-500, n=21 (*p = 0.58)	90%*
20%	9.5%	< 100, n=26	20%

The study would not have been possible without:

- Dr. Francois Nosten
- Mr. Stephane Proux and SMRU staffs
- 271 patients who consented to the study
- Diamed Switzerland for giving the tests

